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ABSTRACT

Regulatory agencies around the world require that those involved in producing pharmaceutical products be adequately trained. E-learning can accomplish this, providing consistent delivery and learner assessment. However, there are some unique expectations that regulators and the pharmaceutical industry have of e-learning solutions. These include approved electronic records and signatures that have reliability and integrity, system and application validation, and assessment of learning. While these expectations are a challenge to e-learning courseware producers, they contribute to the production of high quality, robust courseware. (Author)

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# Challenges in Providing e-Learning Solutions in the Regulated Pharmaceutical Industry

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ED 479 421

**Abstract:** Regulatory agencies around the world require that those involved in producing pharmaceutical products be adequately trained. E-learning can accomplish this, providing consistent delivery and learner assessment. However, there are some unique expectations that regulators and the pharmaceutical industry have of e-learning solutions. These include approved electronic records and signatures that have reliability and integrity, system and application validation, and assessment of learning. While these expectations are a challenge to e-learning courseware producers, they contribute to the production of high-quality, robust courseware.

The pharmaceutical industry includes those firms that manufacture prescription and over-the-counter drug products, active pharmaceutical intermediates, biotech pharmaceuticals, and those products derived from human blood and plasma. Manufacturers in this sector must provide knowledge and skill training to personnel who develop, manufacture, and test pharmaceutical products making this sector a prime candidate for using web-based e-learning solutions. At the same time, this heavily regulated industry has some unique requirements that must be met in order for e-learning to be used.

We're familiar with the features of elearning. Some of these are of particular interest in the pharmaceutical industry because of the resulting benefits that include:

- Consistency of content and delivery;
- Availability 24/7;
- Availability from any location with a suitable inter-/intra-net access;
- Completing the program at the learner's own pace;
- Inclusion of text, audio, graphical, and video elements; and
- Rapid updates.

Examples of where e-learning is currently being used or implemented include providing:

- Basic regulatory training for personnel working in blood collection centers across the U.S. including large cities as well as very small/remote communities.
- Initial training to temporary workers or contractors.
- Intermediate-level training on how regulations apply in particular jobs.
- Basic and intermediate-level training to clinical investigators and institutional review boards on how to protect people who volunteer to participate in clinical research.

## Regulations, requirements, and expectations

Most industries or sectors consider themselves "special" or "unique". Those of us in the pharmaceutical industry certainly do – in part because we are the most heavily regulated in the world along with the aviation and nuclear power industries. Drug agency inspectors, like those from the Canadian Health Products and Food Branch and the US' Food and Drug Administration, conduct periodic inspections, evaluating the quality systems, buildings and facilities, and manufacturing and laboratory operations. Training is a key element in each of these areas. The set of knowledge and skills these personnel need to know and apply is called, "Good Manufacturing Practice" or GMP.

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Most countries or regions have their own set of these GMP requirements; most of the principles of GMP are the same from country to country, however there are some small differences.

Regulatory requirements are derived not only from what is published as regulations, but also from guidance documents, and best of industry practices that are "feasible and valuable" – a phrase of particular importance with the US FDA. Sometimes these requirements are referred to as "expectations" – which is what the regulatory agencies expect to see implemented by drug manufacturers.

Currently, there are three important expectations related to training of personnel using e-learning solutions:

1. Use of electronic records and electronic signatures that are at least as reliable and trustworthy as their traditional paper or hand-written counterparts.
2. Validation of computerized systems and applications to ensure they function as intended.
3. Assessment of personnel to ensure they have the required knowledge and can (and are) performing their assigned tasks as required.

The first two expectations must be considered as part of the design, development, and implementation of any learning management system or LMS and the e-learning "engine"; the second and third expectations must be considered in the design, development, and implementation of the specific training course applications. These expectations apply to e-learning projects done by contractors/vendors or by pharmaceutical firms themselves.

## Electronic records and electronic signatures

In March 1997, the US FDA published a regulation, "21 CFR Part 11" (FDA 1997) that mandates that whenever electronic documents or an electronic signatures are generated or used to meet an FDA requirement, that they be created, stored, and retrieved in a way that assures their veracity – i.e., their truthfulness and reliability. The FDA had, in isolated but significant situations, discovered firms that had prepared and submitted fraudulent paper documents. The agency was concerned that by using computer technology, those firms intent on committing fraud could do illegal things, faster.

Regulatory agencies in other countries and regions have similar concerns but have not yet established such detailed requirements.

We all saw – or participated in – the work required to make computer systems Y-2-K compliant. For firms regulated by the FDA, Y-2-K was, without exaggeration, a fraction of the effort and expense to achieve "Part 11" compliance. Terms like audit trails, biometric and non-biometric signatures, certifications, and metadata are now part of our lexicon.

Neither the FDA nor the industry had a clear understanding of enormous impact of the regulation when it was published. We are still in a dynamic situation with the FDA as their expectations evolve.

Related to e-learning, Part 11 impacts learning management systems and any e-learning application that creates or stores records or requires someone to "sign" that they have completed a specified action. For example, if an LMS collects and retains assessment results from a learner's session and retains a record of this, an FDA investigator (or an in-house regulatory compliance auditor) could ask simple questions, such as: *"How do you know that this training record for Mr. G. Brown hasn't been modified in any way? How do you know that this is the actual data or record that was generated during the training session? Prove it to me."* Providing suitable – compliant – answers to these questions is the essence of Part 11.

## Validation

Another question that regulatory investigators (and auditors) ask is, *"How do you know that this computer system or web-based training program is doing what it is supposed to do?"* That is the basic question answered through the process of validation. Validation is simply defined as having documented evidence that a computerized system is consistently performing as it was intended.

For new systems or applications that are being created, hardware and software designers utilize the "system life cycle" with defined actions and responsibilities that apply to both the system owner and the developer (or supplier). This approach is not unique to the pharmaceutical industry; the expectations are consistent with ISO standard ISO 9000-3 and recommended practices by the IEEE.

The nine phases are not necessarily a linear path; some are predicated on others being completed while at other times, there may be a re-iterative loop or branch that is appropriate to take. The phases consist of:

1. System idea (including a needs analysis report and a request for proposal [RFP])
2. System plan (defining user requirements specifications [URS] and system requirements specifications [SRS])
3. Design (producing the system design description)
4. Build
5. Test (verifying compliance to the system design)
6. Commission (system acceptance, validation to URS and SRS)
7. Operate
8. Maintain
9. Retire (decommissioning and retiring)

In other words, you:

- Define what must be achieved
- Produce a solution that achieves the goal
- Prove that the goal is being achieved
- Maintain control to ensure that the goal is achieved

Throughout this process, records become the evidence that the activities were done. Pharmaceutical client firms conduct audits of vendors to review the records and assure that procedures are written and are being followed to adequately control the entire process.

Accomplishing some of these activities is consistent with good instructional systems design or ISD practice, while other activities can be a challenge to control. For example, at Learnwright, as we have created web-based GMP training courses, we have been challenged to initiate and follow new rules of practice to comply with validation and change control when developing new programs or making fixes or changes. Key in this is having the proposed change approved, documenting what we are doing, and then adequately testing to assure ourselves and our clients that there have not been any unintended surprises. For creative software developers and ISD professionals, achieving this needed level of control is a discipline that must be developed.

Does this control take more time and energy? Yes. Does it cost more money upfront in the design and development process? Yes. Are there benefits to our clients and to us? Yes – it helps them meet regulatory requirements and helps us have a higher level of comfort that our courseware will work. It is an investment that we can make that builds quality and excellence into what we do.

Is all of this really necessary? Read the article in the July/August 2002 issue *of Technology Review*, entitled "Why Software is So Bad" (Mann 2002). You'll see how inadequate control during design, programming, and testing can result in serious problems.

Am I saying that learning management systems and e-learning courseware have to be developed and validated to the same degree that an implantable pacemaker must be? No. The key is that what we do must ensure that the e-learning solutions we provide are fit for their intended use – a basic definition of quality.

The third regulatory expectation that we mentioned earlier, *Assessment of personnel to ensure they have the required knowledge and can (and are) performing their assigned tasks as required*, is where e-learning technologies can have a unique impact. This is where we, as designers and producers of elearning can leverage our creativity and engineering skills.

## Assessing the learners

Those who have studied the theory of learning and assessment have confirmed a rather intuitive fact: The closer the design of an assessment exercise is to how the job is actually performed, the more confidence we can have that if a person does well on the assessment, the higher the probability that a person can transfer the knowledge and skill into the job. Yes, there are any number of factors that can block transfer, but with that said, the closer the assessment tool is to the job, the better.

A simple example: You are teaching me how to put on a sterile gown – we call them "bunny suits" – so I can working in an aseptic facility making injectable drugs like antibiotics or insulin. You give me a pen and paper test about the sequence of what part of the gown to put on first, second, third, and so on – I'll probably pass. I'm good at that type of fact recall. But my passing that assessment isn't going to tell you much about how I put on that gown – can I put it on in the correct sequence without contaminating it. For that, you want an assessment that is more of a simulation of how the task is actually performed in as close to the "natural" setting as possible.

With that in mind, I would like to show you three examples of how we at Learnwright have attempted to make our assessment strategy as close as possible to how a person in a pharmaceutical or blood products organization would apply certain GMP principles. These are what we call:

- Audit document
- Audit cam
- Audit conversation

The basic premise is that we assign the learner to examine something that they would have familiarity with in their jobs: they are to review documents, watch a person perform a task, and observe a conversation. It each situation, they identify deficiencies (based on other information and content provided or that they should know) and then determine the impact of the problem, state why it is a problem, or select the corrective action that is appropriate. These skills are similar to what an auditor would do during a GMP compliance audit. Hence the term, "audit cam".

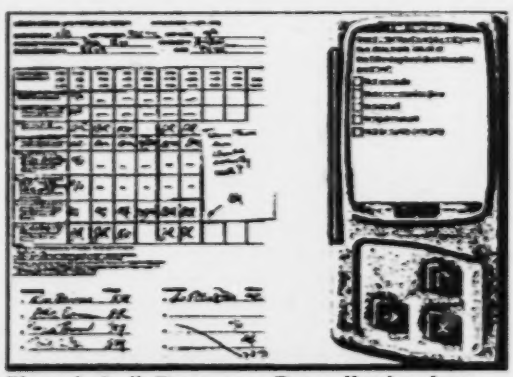

Figure 1. Audit Document – Data collection sheet.



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An audit document is shown in Figure 1. The learner can roll over the document and see that different areas are highlighted. Some are real problems, others are distractors. The system deducts points for incorrect selections. So, if you know the information and select the correct hot spots and answer the follow-up questions correctly, you will keep a high score. If you guess, you will be loosing points, reducing the score.

In this audit document, you can see that a simple horizontal line is used to show that data is not present. In our industry, that is a problem – it should have an "NA" or a "not applicable" marking and include the writer's initials and date written. Clicking on that highlighted zone, I get feedback that I have found a valid problem and then a follow-up question that I need to respond to.

Figure 2. Audit Cam – Warehousing.

An audit cam is shown in Figure 2. The learner first reads a description of a video scenario that they will view – in this case, someone who finds a special "quarantine" label on the floor of the warehouse. Then they will view a 45 to 75 second video of the person doing the task, similar to what they do in their job. A voice-over presents what the person in the video is thinking as he or she performs the job. After completing the video sequence (which they can review without penalty), still-frames from the video are presented that include the problems visually depicted in the video. Here the learner plays the game, 'what's wrong with this picture' – identifying problems and determining their impact. Some of these video segments are "over the top" – most experienced personnel seeing these are on the floor laughing about the poor practices. That's fine – it opens up a part of their mind to the learning process and allows them, through the follow-up questions, to demonstrate that they understand *why* it is a problem or *how* they should properly respond.

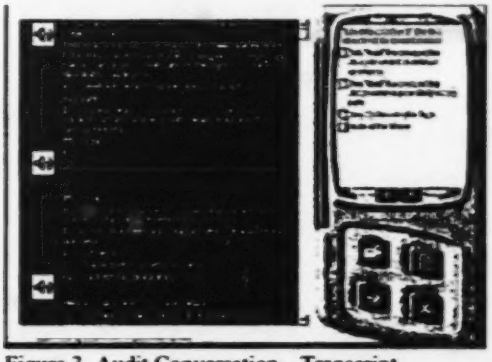

Figure 3. Audit Conversation – Transcript.

An audit conversation is shown in Figure 3. This was first developed because of the needs in the blood industry. If you donate blood, a screener must ask certain questions, in a particular way, in a proper setting. Using audit conversation, the learner will watch and listen to a videotaped conversation and then examine a transcript of that



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conversation. The transcript has sections that are "hot" – again with the distractors and true problems – that the learner can click on. If a problem is found, feedback is given and a follow-up question is asked.

Since all of the scenarios used in the audit documents, audit cams, and audit conversations are based on real-life situations and problems that a person working in that area could reasonably encounter, these are almost simulations that assess the learner's ability to apply GMP knowledge and decision-making skills.

## Conclusion

There are some special requirements in providing e-learning solutions to the pharmaceutical industry: electronic records and signatures, validation, and the need for assessment. Our experience has been that by embracing these requirements, our end product is more stable, controlled, robust, and focused on the true learning and compliance needs of our clients.

## References

FDA (1997) Part 11 – Electronic Records; Electronic Signatures, *Federal Register*, 62 (54), 13429-13466.

Mann, C.C. (2002) Why Software is so Bad, *Technology Review* 105 (6), 33-38.

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